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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,675	01/29/2004	Tom McHale	S63.2-10813US01	5432

490 7590 01/04/2007
VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

SEVERSON, RYAN J

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/767,675	Applicant(s) MCHALE ET AL.	
	Examiner Ryan Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 27-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/06, 3/05, 8/04, 5/04, 4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election **without traverse** of invention I (claims 1-26) in the reply filed on 06 December 2006 is acknowledged.
2. Claims 27-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without traverse** in the reply filed on 06 December 2006.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 38 (the coupling) and 42 (the distal portion).
4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 18 (see figures 2 and 3).
5. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37

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CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-3, 5, 6, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Follmer et al. (5,728,065).** Follmer et al. reference discloses the catheter substantially as claimed, including: a catheter shaft (102), an inflation balloon (106) with proximal and distal waist portions (see Figure 2), and a catheter tip with proximal and distal ends and main and distal shaft portions. The tip is coupled to the inner catheter shaft. The tip is interpreted to be the portion in figure 2 including the distal shaft (122) and the center portion of the shaft with the reinforcements (114). The catheter shaft is interpreted to be the portion with reinforcements (112).
7. Regarding claims 2, 3, 6, and 14 Follmer et al. reference discloses radiopaque markers (124) in column 7, lines 24-25. The marker region is interpreted to be the recess that the marker rests in (see Figure 2).
8. Regarding claim 5, the tip of Follmer et al. reference is round, and therefore is considered radiused.

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9. Regarding claims 15 and 16, the first region is considered the soft tip (122) and the second region is the reinforced region with reinforcements (114). Due to the reinforcements, the soft tip is more flexible than the reinforced region. These reinforcements are entrained stiffening fibers (see Column 7, Lines 9-10). The fibers are interpreted as the ribbons.

10. Regarding claim 17, the catheter of Follmer et al. reference further comprises an outer catheter shaft (104) and the proximal waist portion of the balloon is coupled to the outer shaft (see Figure 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Follmer et al. (5,728,065) as applied to claim 2 above, and further in view of Jacobsen et al. (Patent Application Publication 2003/0,069,522). Follmer et al.

discloses the catheter as described in claim 2 above. However, Follmer et al. reference does not disclose the marker band is an MRI marker. Attention is drawn to Jacobsen et al. reference, which teaches and MRI marker may be used with a catheter (see Paragraph 124) to allow the placement of the catheter to be viewed using MRI equipment during a procedure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the marker of Follmer et al. reference be an MRI marker, as taught by Jacobsen et al. reference, to allow the placement of the catheter to be viewed using MRI equipment during a procedure.

12. Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Follmer et al. (5,728,065) as applied to claim 1 above, and further in view of Ellis et al. (6,395,008). Follmer et al. discloses the catheter as described in claim 1 above.

However, Follmer et al. reference does not disclose a hub portion on the catheter. Attention is drawn to Ellis et al. reference, which teaches a hub portion (74) may be formed on a catheter tip to help create a tighter connection between the balloon and the shaft. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a hub with the tip, as taught by Ellis et al. reference, to help create a tighter connection between the balloon and the shaft.

13. Regarding claim 8, the hub portion is shown integrally formed with the tip section (see the dotted lines in Figure 8).

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14. Regarding claims 9-11, Follmer reference shows a radiopaque marker insert molded with the outer surface flush with the outer surface of the tip (see Figure 2).

15. **Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Follmer et al. (5,728,065) as applied to claim 1 above, and further in view of Ressemann et al. (5,921,958).** Follmer et al. discloses the catheter as described in claim 1 above. However, Follmer et al. reference does not disclose a spring stiffener element. Attention is drawn to Ressemann et al. reference, which teaches a stiffening spring (386 – see Figure 18) be used with a catheter to give it strength in the axial direction when being pushed through a lumen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a spring stiffener with the catheter, as taught by Ressemann et al. reference, to give it strength in the axial direction when being pushed through a lumen.

16. **Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Follmer et al. (5,728,065) as applied to claim 1 above, and further in view of Gambale et al. (6,447,522).** Follmer et al. discloses the catheter as described in claim 1 above. However, Follmer et al. reference does not disclose the catheter tip is coupled to the catheter shaft by heat bonding. Attention is drawn to Gambale et al. reference, which teaches two shafts may be coupled by heat bonding (see Column 7, Lines 12-18) to maintain a secure connection there between. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to couple the catheter tip to the catheter shaft using heat bonding, as taught by Gambale et al. reference, to maintain a secure connection there between.

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17. **Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Follmer et al. (5,728,065) as applied to claim 1 above, and further in view of Cathcart et al. (5,951,585).** Follmer et al. discloses the catheter as described in claim 1 above. However, Follmer et al. reference does not disclose the catheter tip is coupled to the catheter shaft by radio-frequency (RF) welding or using adhesive. Attention is drawn to Cathcart et al. reference, which teaches either RF welding or the use of adhesives to join a shaft to another tubular member (see Column 8, Lines 47-49) to maintain a secure connection there between. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to couple the catheter tip to the catheter shaft using either RF welding or adhesives, as taught by Cathcart et al. reference, to maintain a secure connection there between.

18. **Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Follmer et al. (5,728,065) as applied to claim 1 above, and further in view of Imran et al. (5,766,203).** Follmer et al. discloses the catheter as described in claim 1 above. However, Follmer et al. reference does not disclose the catheter is a stent delivery catheter. Attention is drawn to Imran et al. reference, which teaches a balloon catheter can be used to deliver a stent to provide permanent support to a weakened vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the catheter of Follmer et al. reference as a stent delivery catheter, as taught by Imran et al. reference, to deliver a stent to provide permanent support to a weakened vessel.

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19. Regarding claim 22, Imran et al. reference discloses a stent mounted about the balloon (see Figure 8C).

20. Regarding claim 23, the stent is an inflation expandable stent (see Column 8, Lines 36-41).

21. Regarding claim 24, the stent can be self-expanding (see Column 8, Line 56).

22. **Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Follmer et al. (5,728,065) as applied to claim 1 above, and further in view of Feingold et al. (6,162,229).** Follmer et al. discloses the catheter as described in claim 1 above. However, Follmer et al. reference does not disclose the catheter tip include a triangular shaped portion. Attention is drawn to Feingold et al. reference, which teaches a tip may be triangular in shape (see Figure 17C) to allow a smaller profile tip to be employed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to shape the tip of the catheter in a triangular manner; as taught by Feingold et al. reference, to allow a smaller profile tip to be employed.

Conclusion

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Thursday 7:00 - 5:30.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ryan Severson
December 21, 2006



ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

12/22/06